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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,201	11/17/2003	Gerald McMahon	034536-0684	9575

22428 7590 12/17/2004

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

RAYMOND, RICHARD L

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/713,201

Applicant(s)

MCMAHON ET AL.

Examiner

Richard L. Raymond

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 6-15 and 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 16-25 and 30-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 04/19/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: SINICAS printout

## **DETAILED ACTION**

### ***Specification***

1. It is requested that a status paragraph be added as the first paragraph of the specification.

### ***Election/Restrictions***

2. Pursuant to the requirement for election of species, applicants have elected 3-methyl-4-[4-(trifluoromethyl)phenylaminocarbonyl]-pyrazole, an N-(4-substituted-phenyl) pyrazolylcarboxamide. Claims 1-5, 16-25 and 30-43 are readable thereon. Claims 6-15 and 26-29 stand withdrawn as not being readable on the elected species.

### ***Improper Markush Rejection***

3. Claims 1-5, 16-25 and 30-43 are rejected as being improper Markush claims in the definition of the A, B, D, E, F, G and J ring variables and ring substituents thereon. So substituted, the resulting total heterocyclic compounds lack a common core and are structurally diverse and patentably distinct one from the others. A reference anticipating one under 35 USC 102 would not be reference against the others under 35 USC 103. Diverse fields of search in the different subclasses of classes 548 and the corresponding subclasses in use class 514 as well as diverse searches in STN/CAS are involved. Limitation of the claims to N-(4-substituted-aryl) pyrazolylcarboxamides, encompassing the elected species, will overcome this rejection.

4. The claims have been searched to the extent that they read on the above grouped invention.

***Obviousness-type Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-4 and 30-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of parents U.S. Patent No. 6, 316,479 and U.S. Patent No. 6,649,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because the N-phenyl and N-pyridyl isoxazolylcarboxamides of the patents anticipate the present broad claims which merely recite "heteroaryl carboxamides".

***Claim Rejections - 35 USC § 112***

7. Claims 1-4 and 30-43 are rejected under 35 U.S.C. 112, first paragraph and second paragraphs. First, the specification, while being enabling for specific

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carboxamides, does not reasonably provide enablement for any and all amides.

Secondly, the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Statements of biological activity do not sufficiently define chemical structure and accordingly, the claims are indefinite as to what structures are actually intended.

8. Claims 30-36 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of specific diseases, does not reasonably provide enablement for the prevention of such diseases and for the treatment of all cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Prevention requires different enablement than treatment, and all the treatments of all cancers are not deemed supported.

***Claim Rejections - 35 USC § 102 / 35 USC § 103***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-5, 16-22, 24 and 32 are rejected under 35 U.S.C. 102(a or b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of the Eicken et al., Sanfilippo et al., Atwell et al., Huppatz, Carter et al. and Wrzeciono et al. Chemical Abstracts references. With respect to these references see the corresponding STN/CAS printouts, which disclose specific N-(4-substituted-phenyl) pyrazolylcarboxamides within the present claims. Where not anticipated, the compounds within the present claims are generically disclosed and/or are the simple homologs and analogs of the specific compounds of the references. In the absence of a showing of unexpected properties, no patentable significance is seen in the present selection.

13. The above art has not been applied against the specific 4-substituted compounds of claims 23 and 25.

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**STN/CAS Search Results**

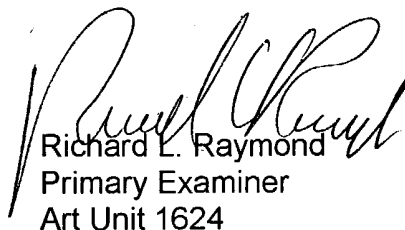
14. The enclosed copy of the complete STN/CAS search (113 answers covering applicants' broad N-aryl pyrazolylcarboxamides) is for applicants' consideration in divisional filings.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard L. Raymond whose telephone number is (571) 272-0673. The examiner can normally be reached on Monday-Thursday, 10:00 AM-8:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Richard L. Raymond  
Primary Examiner  
Art Unit 1624

rr  
December 11, 2004